UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

04-30182-MAP

WESTERN DIVISION

CIVIL ACTION NO.

HISTOGENICS CORPORATION,
Plaintiff

vs.

SRS INTERNATIONAL CORPORATION,
Defendant

AMENDED COMPLAINT

JURISDICTION AND PARTIES

1. The plaintiff, Histogenics Corporation (hereinafter "Histogenics") is, and at all times mentioned has been, a corporation organized and operating under the laws of the Commonwealth of Massachusetts with a place of business at 116 Pleasant Street, Easthampton, Massachusetts.

2. The defendant, SRS International Corporation (hereinafter "SRS") is a corporation with a place of business at Suite 1000, 162 K Street, NW, Washington, D.C.

3. Subject matter jurisdiction is based upon diversity of citizenship, 28 U.S.C. § 1332, the amount in controversy exceeding $75,000, exclusive of interest and costs.

4. This Court has jurisdiction over SRS International pursuant to Massachusetts General Laws Chapter 223A by virtue of the transaction of business here.

STATEMENT OF FACTS

5. Histogenics is in the business of investigating, performing research, developing, creating, licensing and ultimately marketing replacement tissue for medical implantation in the human body.

6. SRS is in the business of assisting medical science innovators in the attainment of governmental licensure for medical products, including but not limited to, the provision of regulatory and clinical guidance in the coordination, initiation and monitoring of clinical trials for governmental approval and licensure for the distribution of medical devices and materials.

7. On April 11, 2001, Laurence Tarrant and John Todhunter, the presidents of Histogenics and SRS, respectively, executed a "Master Agreement for Services". A copy of the same is appended as Exhibit A.

8. On that same day, those same individuals executed the first "Task Order". This Task Order pertained to the development, program design, coordination, management, monitoring and implementation for both non-clinical and clinical studies; regulatory and scientific strategic consultations; Federal Drug Administration regulatory affairs services, including the application and obtainment of licensure for the marketing and distribution of a tissue replacement implant system for repair of cartilage defects in, and around, the human knee. A copy of the Task Order is appended as Exhibit B.

9. After execution of both the Master Agreement and initial Task Order, SRS proposed changes, including the fees to which it would be entitled, as well as changes in the timetable for the clinical trials, presentation to governmental agencies and licensure. Histogenics agreed to some of the modifications, but did not agree to others.

10. During the period from April 11, 2001 until August 27, 2003, Histogenics paid SRS pursuant to the agreement.

11. During that period of time, SRS did not adhere to the milestones established at the inception of the agreement, or mutual modification thereof, resulting in delays in achieving clinical trials. SRS delayed in responding to Histogenics regulatory questions and gave limited attention to clinical protocol requirements. It failed to prepare support letters and gave limited attention to clinical site budget concerns and insurance issues. SRS provided limited initiative regarding assistance to clinical site coordinators as well as a limited effort regarding implementation of protocol amendments. These attentive deficiencies resulted in the need for oversight by Histogenics of the clinical and regulatory efforts and caused compounded delays in the initiation of clinical enrollment and the acquisition of regulatory licensure.

12. SRS committed a material breach of its agreement with Histogenics to provide services for the clinical development, regulatory assistance and ultimately, licensure, for the distribution of Histogenics' products.

13. As a consequence of that breach, Histogenics has sustained substantial monetary damages associated with the delay of the licensure of its products.

14. Therefore, on August 27, 2003, through counsel, Histogenics issued a Notice of Immediate Termination of the Master Agreement for Services with SRS. A copy of that notice is appended as Exhibit C. The Master Agreement for services expressly provides in Article Z for termination by Histogenics upon thirty (30) days notice without cause and it is subject to immediate termination for material breach or cause. (Exhibit A).

15. As of the date of the Notice of Termination, Histogenics had paid SRS substantial sums for services under the Master Services Agreement. In addition to the performance failings of SRS, Histogenics determined that it had been overcharged in excess of $200,000 for those services actually provided by SRS, based upon the failure of SRS to achieve various performance milestones.

16. As part of the Notice of Termination, Histogenics specifically requested the immediate delivery of all work product and files pertaining to the clinical development and application for licensure of the Histogenics tissue replacement system.

17. SRS has refused and failed to provide that documentation, either in paper or electronic form. Consequently, Histogenics was compelled to engage counsel to draft a request to the Federal Drug Administration under the Freedom of Information Act for Histogenics' material with detrimental and costly delay.

18. In response to the Notice of Termination, based upon a material breach of the Agreement by SRS, SRS indicated that it had not breached the Agreement and would acquiesce in the termination only in return for the payment by Histogenics

to SRS of $593,286, notwithstanding the thirty (30) day termination provision in Article Z. (Exhibit A).

19. The Master Agreement between Histogenics and SRS contains a provision for dispute resolution requiring that the parties first pursue non-binding mediation, and if no resolution is obtained, to proceed with binding arbitration. (Exhibit A). On October 8, 2003, Histogenics, through counsel submitted a Demand for Arbitration to the Commercial Division of the American Arbitration Association and, per the advice of an administrator at the American Arbitration Association, checked off the box indicating Histogenics' willingness, in accordance with the Master Agreement, to proceed with mediation prior to binding arbitration. A copy of the Demand for Arbitration reflecting that it had been sent to SRS's counsel, John D. Pellegrin, is appended as Exhibit D.

20. On October 27, 2003, the American Arbitration Association returned to Histogenics' counsel the Demand for Arbitration/Mediation as well as the entry fee of $2,750. Inquiry at the American Arbitration Association as to the reason for the return of the submittal was made, and counsel for Histogenics was advised that because the Master Agreement did not specify the American Arbitration Association as the mediator/arbitrator and because John D. Pellegrin, counsel for SRS, had expressed an unwillingness to use the American Arbitration Association as a forum for resolution of the dispute, the submittal by Histogenics for arbitration/mediation was returned. See Exhibit E, Affidavit of L. Jeffrey Meehan.

21. On October 31, 2003, counsel for Histogenics wrote to John D. Pellegrin, counsel for SRS International, requesting that SRS agree to use the American Arbitration

Association as a forum for mediation and, if necessary, binding arbitration, of the instant dispute. Neither Mr. Pellegrin nor SRS responded to this request. See Exhibits E and F.

22. Despite repeated demands and requests to engage in mediation and, if necessary, binding arbitration for the resolution of this dispute as contemplated and provided for in the Master Agreement, SRS has refused mediation and arbitration in breach of the Agreement.

23. The conduct of SRS in failing to perform its obligations under the Master Agreement; in overbilling and collecting from Histogenics fees for services not rendered; for failing to adhere to the timetable established for the clinical development and application for licensure of Histogenics medical devices; for refusing, upon specific request, to tender to Histogenics its work product and files; for refusing to engage in mediation and, if necessary, binding arbitration SRS has committed unfair and deceptive acts or practices, and acted in bad faith in violation of Massachusetts General Laws Chapter 93A.

24. On December 24, 2003 SRS filed suit against Histogenics and others in the Superior Court for the District of Columbia.

25. The suit by SRS was removed by counsel for Histogenics to United States District Court for the District of Columbia, and thereafter motions were filed for dismissal on behalf of Histogenics and the other defendants.

26. On August 16, 2004 Judge Royce C. Lamberth of the United States District Court for the District of Columbia allowed the defendants' motions to dismiss, in part because of a refusal or failure by SRS to participate in mediation and/or

arbitration as provided in the agreement with Histogenics, and otherwise dismissed the complaint of SRS for lack of personal jurisdiction. Copies of Judge Lamberth's order and memorandum of decision are appended together as Exhibit G.

RELIEF SOUGHT

That SRS be ordered to participate in mediation and if necessary, binding arbitration before a panel of three (3) arbitrators, under the jurisdiction of and subject to the Commercial Arbitration Rules of the American Arbitration Association at Springfield, Massachusetts and 9 U.S.C. § 4;

THE PLAINTIFF
HISTOGENICS CORPORATION

By _____
L. Jeffrey Meehan, Esquire
Doherty, Wallace, Pillsbury
and Murphy, P.C.
1414 Main Street, Suite 1900
Springfield, MA 01144
(413) 733-3111
(413) 734-3910 (fax)
B.B.O. Number 341440